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From-LAHIVE & COCKFIELD, LLP

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Serial No.: 09/374,554

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Group Art Unit No.: 1655

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the matter of the Application of: Shyjan, et al.

Application No.: 09/374,554

Filing Date: August 13, 1999

For: *Methods and Compositions for the Identification and Assessment of Cancer Therapies*

Attorney Docket No.: MRI-005CP2CPA

Group Art Unit: 1655

Examiner: Goldberg, J.

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Preliminary to the examination of the above-referenced application, entry of the below amendments and consideration of the remarks provided are respectfully requested.

In the Claims:

Please amend the pending claims 3, 18, and 32-33 as follows:

Sub
33

3. (Amended) A method for determining whether TAXOL cannot be used to reduce the growth of cancer cells, comprising the steps of:

- a) obtaining a sample of cancer cells;
- b) determining whether said cancer cells express one or more genes selected from the group consisting of the resistance genes identified in Tables 8A, 9A, 9B, 9C, 9D, 10A, and 11A; and
- c) identifying that TAXOL cannot be used to reduce the growth of said cancer cells when one or more of said genes is expressed by said cancer cells.

Sub 6/11
18. (Amended) A method for determining whether TAXOL cannot be used to reduce the growth of cancer cells, comprising the steps of:

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- a) obtaining a sample of cancer cells;
 - b) exposing the cancer cells to TAXOL;
 - c) determining the level of expression in the cancer cells of one or more genes selected from the group consisting of the resistance genes identified in Tables 8A, 9A, 9B, 9C, 9D, 10A, and 11A in the sample exposed to TAXOL and in a sample of cancer cells that is not exposed to TAXOL; and
 - d) identifying that TAXOL cannot be used to reduce the growth of said cancer cells when the expression of one or more of said genes is increased in the presence of TAXOL.

Sub 6/14
32. (Amended) A method for determining whether treatment with TAXOL should be continued in a cancer patient, comprising the steps of:

- Ag
- a) obtaining two or more samples comprising cancer cells from a patient during the course of TAXOL treatment;
 - b) determining the level of expression in the cancer cells of one or more genes selected from the group consisting of the resistance genes identified in Tables 8A, 9A, 9B, 9C, 9D, 10A, and 11A in the two or more samples; and
 - c) discontinuing treatment when the expression level of one or more of said genes increases during the course of treatment.

Sub 6/15
33. (Amended) A method for determining whether treatment with TAXOL should be continued in a cancer patient, comprising the steps of:

- a) obtaining two or more samples comprising cancer cells from a patient during the course of TAXOL treatment;
- b) determining the level of expression in the cancer cells of one or more genes selected from the group consisting of the resistance genes identified in Tables 8A, 9A, 9B, 9C, 9D, 10A, and 11A in the two or more samples; and
- c) continuing treatment when the expression level of one or more of said genes does not increase during the course of treatment.

REMARKS

Entry of this preliminary amendment is respectfully requested and is believed appropriate under 37 C.F.R. §1.115.

Upon entry of this paper, claims 3, 18, and 32-33 have been amended. Support for the foregoing amendments can be found throughout the specification, figures, and claims, as originally filed. Thus, no new matter has been added.

Entry of this amendment is respectfully requested for consideration at first action in this case. If there are any questions concerning the application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,



DeAnn F. Smith

Registration No. 36,683

Attorney for Applicants

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400
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